REMARKS

Claims 1-8 are pending in the application. These claims were rejected as follows:

Claims / Section	35 U.S.C. Sec.	References / Notes
7 & 8	§112, Second Paragraph Indefiniteness	• Acronym used
1–8	§102(b) Anticipation	• Teshima (U.S. Patent No. 6,272,470).

Applicant has amended claims 7 and 8 to address the acronym issues noted by the Examiner, and has also provided discussion for distinguishing the present invention from the art cited against it.

Applicant has added new claims 9–11 for consideration by the Examiner. Support for these claims can be found in the Specification at paragraphs [0008, 0013, and 0015] respectively.

Applicant's use of reference characters below is for illustrative purposes only and is not intended to be limiting in nature unless explicitly indicated.

35 U.S.C. §112, SECOND PARAGRAPH INDEFINITENESS

1. Applicant has amended claims 7 and 8 to spell out the acronym used in the claims, pursuant to the Examiner's suggestion.

Applicant has complied with the Examiner's suggestion for amending claims 7 and 8 and respectfully requests that the Examiner withdraw this rejection from the application.

35 U.S.C. §102(b), CLAIMS 1–8 ANTICIPATION BY TESHIMA

2. Teshima does not deal with a clinical study and does not teach or suggest generating and distributing an input platform of a clinical study.

In the OA, on pp. 2–3, he Examiner rejected claim 1 as being anticipated by Teshima. The Examiner stated:

> As per claim 1, Teshima teaches a method to input and store data for a clinical study, comprising:
>
> - Generating an input platform program for an input of data of a clinical study (column 8, lines 1 - 50);
> - Distributing the input platform program to input locations (column 6, lines 45 - 58 where the locations are distributed through the Internet);
> - Calling up and activating the input platform program dependent on a participant characteristic (column 13, lines 35 - 46 where the web page is called up), the participant characteristic being linked with a patient participating in the clinical study (column 12, lines 55 - 65);
> - Inputting the data at an input location via an input platform generated by the input platform program (column 10, lines 23 - 31); and
> - Storing the input data (column 11, lines 31 - 33).

Applicants respectfully disagree with this characterization of the teaching of Teshima. First of all, Teshima does not relate to clinical studies—rather Teshima deals merely with normal patient examination in a clinical setting.

Teshima concerns a clinical electronic acquisition system in which a plurality of hospitals are connected via the Internet for information exchange. Within the individual hospitals the information exchange ensues via a local area network. The access to specific information ensues after identifying a patient via a patient card and likewise after a user of the data provides proper authorizing

identification via an operator card to access the data. The participating doctors, examining technicians, and other data users can log into the system with the operator card.

At the same time, the scope of the information that can be retrieved or input is determined by the operator card (see column 8). Given a networked medical information system, it must also be possible to retrieve a great deal of different data from various locations. Various data exchange protocols that are explained in detail in Figures 10 through 14 and the associated specification serve for this. Although this general medical information system described there allows various medical information to be provided to an authorized user or also allows new medical data to be input into the system, it does not support the implementation of a clinical study in a particular manner, as is required by the claims of the present invention.

Clinical studies are not to be understood as any form of generic medical examination. The term is known to one of ordinary skill in the art as a scientific test of the effectiveness and safety of a therapeutic agent (as a drug or vaccine) using consenting human subjects. (See Merriam-Webster's Third New International Dictionary (computer version 3.0, 2003)) for the definition of "clinical trial", which is synonymous with the term "clinical study" used herein.

A system and method dealing with a clinical study is not the same as one dealing with mere medical examinations, as is dealt with by Teshima. It is clear that it is not sufficient for the implementation of a clinical study to process all data present in a medical information system without filtering. Data of patients that

participate in a specific study and those that do not participate in a specific study would then not be differentiated. A collection of data of various patients and a subsequent common evaluation of the study data would not be possible according to what is disclosed by Teshima.

According to the present invention, an input mask specifically generated for a specific study (i.e., the input platform program) is presented to the user (i.e., a person authorized for input, such as a doctor, for example) in the event that it is recognized that a patient participates in the clinical study. At the participating input locations for the clinical study, it can also be detected whether a patient participates in the clinical study; a participant attribute is assigned to each participating patient. A clinical study can only be effectively supported via this (in comparison to Teshima) additional information.

Since clinical studies were not disclosed at all in Teshima, no statements regarding their implementation of suitable measures are found there as well. In particular, the further inventive feature that a platform program is generated and distributed for the input of study data is also not mentioned there.

The Examiner appears to equate Teshima's clinical recording system (8:3–5) to the input platform program of the present invention in addressing the generating step of the present invention (citing 8:1–50). However, the Examiner then points to Teshima's disclosure at 6:45–58 for disclosing the present invention's step of distributing the input platform programs to input locations. Based on how the Examiner equated the elements under the generating step, this would required Teshima to then disclose distributing the clinical recording

system to input locations, as required by the claim. Teshima does not, however do this. Instead, at the sections cited by the Examiner (6:45–58), Teshima simply discloses interconnecting an already-installed clinical recording system via the Internet so that they can communicate with one another. Furthermore, the present invention requires that the input platform is called up and activated *dependent upon a participant characteristic*. To the extend that the Examiner is equating Teshima's clinical recording system with the input platform program of the present invention, Teshima fails to disclose a calling up and activating dependent on a participant characteristic. In the portion cited by the Examiner (13:35–46), the access via the WWW browser does not occur dependent upon a participant characteristic, but rather occurs *independently* of the participant characteristic, and therefore does not read on the claimed element.

For these reasons, the Applicants assert that the claim language clearly distinguishes over the prior art, and respectfully request that the Examiner withdraw the §102 rejection from the present application.

CONCLUSION

Inasmuch as each of the objections have been overcome by the amendments, and all of the Examiner's suggestions and requirements have been satisfied, it is respectfully requested that the present application be reconsidered, the rejections be withdrawn and that a timely Notice of Allowance be issued in this case.

Any shortages of fees due may be charged to, and any overpayments may be credited to, deposit account no. 50-1519.

Respectfully submitted,

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